



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

D1107B

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JAN 16 1997

Marc Beige, President
Rubie's Costume Co., Inc.
999 Gould St.
New Hyde Park, New York 11040

re: 29-NYK-97

Dear Mr. Beige:

In October 1996 an FDA investigator from this office inspected your firm and collected labeling and samples of "Rubie's Star Quality Glow Cream Makeup" and "Rubie's Lights Off Glow Nail Polish" which your firm distributes.

Our review of the labeling for and analysis of the "... Glow Cream Makeup" and "... Glow Nail Polish", and investigation reveals that the products contain zinc sulfide. The products are cosmetics as defined at Section 201(I) of the Food, Drug And Cosmetic Act (the Act). The zinc sulfide is a color additive as defined in Section 201(t) of the Act. Since there is no color additive regulation allowing for the use of zinc sulfide as a colorant in cosmetic products, the glow cream makeup and glow nail polish are adulterated under Section 601(e) of the Act. (That is, they are not hair dyes and they are, or they bear or contain, a color additive which is unsafe within the meaning of Section 721(a) of the Act).

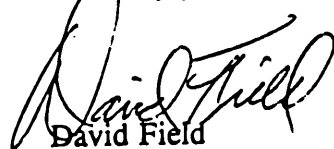
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or intend to take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations and a timetable for correction.

Rubie's Costume Co., Inc. January 1997 page 2

Your reply should be sent to the Food and Drug Administration, New York District Office, at the above address, Attention: William Friedrich, Compliance Officer.

Sincerely yours,



David Field
Acting District Director
New York District

cc: President


Rubie's Costume Co., Inc. January 1997 page 3

O: addressee


cc: HFR-NE1

cc: HFS-105 (Attn.: Allen R. Halper)

cc: HFS-607

cc: HFA-224

cc: HFI-35 (purged) 

cc: HFC-210/DCMO(CFN 2434477)


cc: HFR-NE1


cc: HFR-NE100

cc: HFR-NE140

cc: HFR-NE150

cc: HFR-NE1500(Vitillo/Mooney)

cc: Warning letter file

cc: EF 

cc: circ/chrono

cc: WF rubies.1tr